SECTION 5 – 510(K) SUMMARY

Submitted by: Biomet Trauma
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OCT 29 2013

Contact Person: Suzana Otaño, Global Project Manager, Regulatory Affairs

Date Prepared: June 17, 2013

Proprietary Name: ALPS 2.5mm Inline Fusion Plate

Common Name: Plate, Fixation, Bone

Classification Name: Single/multiple component metallic bone fixation appliances and accessories (21 CFR § 888.3030)

Predicate Devices: The ALPS 2.5mm Inline Fusion Plate is substantially equivalent to currently marketed Fracture and Fusion Plating System (K093474) and the Mini Fragment Plating System (K061748).

Device Description: The ALPS 2.5mm Inline Fusion Plate consists of a 2.5mm Titanium alloy fusion plate offered to be used with non-locking, locking and variable angle screws manufactured from Titanium alloy and CoCr for bone fixation and the management of fractures, fusions, revisions and reconstructive surgeries.

Indications for Use: The system is intended for use in stabilization and fixation of fractures, revision procedures, fusions, reconstructions (osteotomy) and non-unions of the bones of the hand, foot, wrist, ankle, finger, toe, humerus, olecranon, clavicle, scapula and pelvis, particularly in osteopenic bone. The system can be used in both adult and pediatric patients (adolescents [>12 – 21 years of age]), where the implant would not cross open epiphyseal plates in skeletally immature patients.

Technological Characteristics: The technological characteristics of the ALPS 2.5mm Inline Fusion Plate are similar to the predicate devices including design, dimensions and material.

Summary of Substantial Equivalence:

The ALPS 2.5mm Inline Fusion Plate is substantially equivalent to currently marketed devices as demonstrated with pre-clinical data including axial load construct testing and evaluation of galvanic corrosion potential. No new issues of safety or efficacy have been raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 29, 2013

Biomet, Inc.
Ms. Suzana Otaño
Global Project Manager, Regulatory Affairs
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581

Re: K131867
Trade/Device Name: ALPS 2.5mm Inline Fusion Plate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Date: September 30, 2013
Received: October 1, 2013

Dear Ms. Otaño:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 – INDICATIONS FOR USE STATEMENT

510(k) Number: K131867

Device Name: **ALPS 2.5mm Inline Fusion Plate**

Indications For Use:

Intended for use in stabilization and fixation of fractures, revision procedures, fusions, reconstructions (osteotomy) and non-unions of the bones of the hand, foot, wrist, ankle, finger, toe, humerus, olecranon, clavicle, scapula and pelvis, particularly in osteopenic bone. The system can be used in both adult and pediatric patients (adolescents [>12 – 21 years of age]), where the implant would not cross open epiphyseal plates in skeletally immature patients.

Prescription Use X AND/OR Over-the-Counter
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices

Page 1 of 1